IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

IN RE: TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION)	
THIS DOCUMENT RELATES TO:	_	Civil Action No. 05-360 (KAJ)
)	CONSOLIDATED
C.A. Nos.: 05-365, 05-390, 05-394, 05-426,)	
05-450, 05-467, 05-475, 05-482,)	
05-516, 05-695)	
)	

ABBOTT'S ANSWER TO END PAYOR PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT

Respondent Abbott Laboratories ("Abbott"), by its undersigned attorneys, hereby answers End Payor Plaintiffs' Consolidated Class Action Complaint ("Complaint"), on knowledge as to itself and otherwise on information and belief, as follows:

- 1. Paragraph 1 contains a description of this proceeding and legal conclusions that require no answer. Admit only that Defendants manufacture and market a fenofibrate drug product under the tradename TriCor, and that Abbott's sales of TriCor exceeded \$750 million in 2004. Abbott otherwise denies the allegations in paragraph 1.
- 2. Paragraph 2 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 2.
- 3. Paragraph 3 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 3.
- 4. Paragraph 4 contains legal conclusions that require no answer. Admit only that paragraph 4 purports to quote an unspecified Fournier document. Without a cite to a specific document, Abbott is without sufficient knowledge or information to form a belief as to

the truth of the allegations in paragraph 4. Abbott otherwise denies the allegations in paragraph 4.

- 5. Admit that plaintiffs do not challenge Abbott's and Fournier's right or ability to apply to the FDA for approval of new fenofibrate formulations. The second sentence of paragraph 5 contains a description of plaintiffs' claims in this proceeding and requires no answer. Abbott otherwise denies the allegations in paragraph 5.
- 6. The allegations in paragraph 6 regarding what can be "legally substitute[d]" are legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 6.
 - 7. Denied.
 - 8. Denied.
- 9. Paragraph 9 contains a description of this proceeding that requires no answer. Abbott otherwise denies the allegations in paragraph 9.
- 10. Paragraph 10 contains a description of this proceeding that requires no answer. Abbott otherwise denies the allegations in paragraph 10.
- 11. Paragraph 11 contains a description of this proceeding that requires no answer. Abbott otherwise denies the allegations in paragraph 11.
- 12. Paragraph 12 contains a description of this proceeding that requires no answer. Abbott otherwise denies the allegations in paragraph 12.
- 13. Paragraph 13 contains a description of this proceeding that requires no answer. Abbott otherwise denies the allegations in paragraph 13.
 - 14. Paragraph 14 contains legal conclusions that require no answer.
 - 15. Admit only that venue is proper against Abbott in this judicial district.

- 16. Admit only that plaintiffs purport to bring this action on behalf of themselves and other similarly situated and purport to define a class. Abbott denies that class treatment is proper in this case. Additionally, paragraph 16 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 16.
- 17. Admit only as to Abbott, except that the last sentence of paragraph 17 contains legal conclusions that require no answer.
- 18. Abbott is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 18, and therefore denies.
 - 19. Denied.
- 20. Abbott is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 20, and therefore denies.
 - 21. Denied.
 - 22. Admitted.
 - 23. Admitted.
 - 24. Denied.
 - 25. Admitted.
 - 26. Paragraph 26 contains legal conclusions that require no answer.
 - 27. Paragraph 27 contains legal conclusions that require no answer.
 - 28. Paragraph 28 contains legal conclusions that require no answer.
 - 29. Paragraph 29 contains legal conclusions that require no answer.
- 30. Admit only that paragraph 30 purports to describe and quote from the cited documents. Abbott states that those documents speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 30.

- 31. Admit only that paragraph 31 purports to describe the cited document. Abbott states that the document speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 31.
- 32. Admit only that paragraph 32 purports to describe the cited document. Abbott states that the document speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 32.
 - 33. Paragraph 33 contains legal conclusions that require no answer.
 - 34. Paragraph 34 contains legal conclusions that require no answer.
 - 35. Paragraph 35 contains legal conclusions that require no answer
 - 36. Paragraph 36 contains legal conclusions that require no answer.
 - 37. Paragraph 37 contains legal conclusions that require no answer.
 - 38. Paragraph 38 contains legal conclusions that require no answer.
 - 39. Paragraph 39 contains legal conclusions that require no answer.
 - 40. Paragraph 40 contains legal conclusions that require no answer.
 - 41. Paragraph 41 contains legal conclusions that require no answer.
 - 42. Paragraph 42 contains legal conclusions that require no answer.
 - 43. Paragraph 43 contains legal conclusions that require no answer.
 - 44. Paragraph 44 contains legal conclusions that require no answer.
 - 45. Paragraph 45 contains legal conclusions that require no answer.
 - 46. Paragraph 46 contains legal conclusions that require no answer.
 - 47. Paragraph 47 contains legal conclusions that require no answer.
- 48. Admit only that paragraph 48 provides a non-exhaustive description of fenofibrate.

- 49. Admitted.
- 50. Admit only that (i) Novopharm filed an ANDA with the FDA on or around December 14, 1999 for fenofibrate capsule, (ii) the ANDA was later amended, and (iii) Novopharm submitted paragraph IV certifications. To the extent that Paragraph 50 describes the ANDA and the paragraph IV certification, Abbott states that the documents speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 50.
 - 51. Admitted.
- 52. Admit only that (i) Abbott and Fournier sued Novopharm in the United States District Court for the Northern District of Illinois on April 7, 2000, for infringement of the '726 patent, and (ii) Abbott and Fournier sued Impax on August 18, 2000, for infringement of the '726 patent. The allegations in paragraph 52 regarding the 30-month stays are legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 52.
- 53. Admit only that (i) Abbott filed NDA No. 021203 for 54 mg and 160 mg fenofibrate tablets on or around December 10, 1999, which the FDA approved on September 4, 2001, (ii) TriCor capsules were not approved for HDL treatment and (iii) the clinical studies on the HDL effect were performed on capsules. Abbott otherwise denies the allegations in paragraph 53.
- 54. Admit only that (i) Abbott discontinued the marketing of the TriCor capsule formulation at a point following the introduction of the 160 mg and 54 mg TriCor tablet products and (ii) Abbott notified the NDDF that the TriCor capsule products were discontinued. Abbott otherwise denies the allegations in paragraph 54.

- 55. Admit only that (i) Abbott sales representatives stopped detailing the discontinued TriCor capsule product and (ii) Abbott destroyed part of its existing inventory of TriCor capsules. Abbott otherwise denies the allegations in paragraph 55.
- 56. Admit only that the U.S. District Court of the Northern District of Illinois granted summary judgment of non-infringement in favor of Teva on March 19, 2002, and that the court granted summary judgment of non-infringement in favor of Impax on March 26, 2003. Abbott otherwise denies the allegations in paragraph 56.
- 57. Admit only that (i) Teva received final FDA approval to market its 200 mg and 134 mg fenofibrate capsule products and tentative FDA approval to market its 67 mg fenofibrate capsule products on April 9, 2002, and (ii) Teva purports to have begun selling its 200 mg and 134 mg fenofibrate capsule products in April 2002. The allegations in paragraph 57 regarding the "exclusivity period" are legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 57.
- 58. Abbott is without sufficient knowledge or information to form a belief as to the truth as to whether the fenofibrate capsules that Teva had shipped to its customers were returned, therefore denied. Abbott denies the remaining allegations in paragraph 58.
- 59. Admit only that the FDA granted Impax final approval to market its fenofibrate capsule products on October 27, 2003. Paragraph 59 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 59.
- 60. Admit only that (i) Teva filed an ANDA for its 54 mg and 160 mg fenofibrate tablets on June 17, 2002, (ii) Teva submitted Paragraph IV certifications in connection with its ANDA, and (iii) Teva sent Abbott a Paragraph IV certification dated August

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- 21, 2002. Abbott states that the certification speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 60.
- 61. Admit only that (i) Abbott and Fournier filed Civil Action No. 02-1512 against Teva for infringement of the '726 Patent, the '670 Patent and the '405 Patent on October 4, 2002, and (ii) Teva provided samples and technical details of its fenofibrate tablets to Abbott and Fournier. Abbott otherwise denies the allegations in paragraph 61.
 - 62. Paragraph 62 contains legal conclusions that require no answer.
 - 63. Admitted.
 - 64. Admitted.
 - 65. Admitted.
- 66. Admit only that Abbott and Fournier filed Civil Action No. 03-847 against Teva for infringement of the '552 patent on August 29, 2003. Paragraph 66 otherwise contains legal conclusions that require no answer.
- 67. Admit only that Abbott submitted NDA No. 021656 to the FDA on October 29, 2003. Abbott otherwise denies the allegations in paragraph 67.
 - 68. Admitted.
 - 69. Admitted.
 - 70. Admitted.
- 71. Admit only that Abbott and Fournier filed a patent infringement action Civil Action No. 04-0047 against Teva for infringement of the '881 patent on January 22, 2004. Paragraph 71 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 71.

- 72. Admit only that the FDA granted tentative approval to Teva's Tablet ANDA on March 5, 2004. Paragraph 72 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 72.
- 73. Admit only that (i) on or around November 5, 2004, Abbott received approval to market 145 mg and 48 mg fenofibrate tablets and began marketing thereafter, (ii) some time after November 5, 2004, Abbott ceased marketing the 160 mg and 54 mg fenofibrate tablets, and (iii) the labels for Abbott's fenofibrate products speak for themselves and should be read as a whole. Abbott denies the remaining allegations in paragraph 73.
- 74. Admit only that (i) Abbott discontinued the 54 mg and 160 mg TriCor tablets and (ii) Abbott notified the NDDF that the 54 mg and 160 mg tablets were discontinued. Abbott otherwise denies the allegations in paragraph 74.
 - 75. Paragraph 75 contains legal conclusions that require no answer.
- 76. Admit only that (i) on May 6, 2005, the Court ruled that Teva's tablet product does not infringe the '552 Patent, the '670 Patent, or claim 9 of the '405 Patent, and (ii) on May 6, 2005, Abbott notified the NDDF that the TriCor 160 mg and 54 mg tablet products were discontinued. The allegations in paragraph 76 regarding the automatic stay are legal conclusions that require no answer. Abbott otherwise denies the remaining allegations in paragraph 76.
 - 77. Admitted.
- 78. Admit only that Abbott and Fournier sent a letter to the Court on May 16, 2005. The document speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 78.

- 79. Admit only that on June 8, 2005, Abbott announced that it had settled its patent dispute with Teva. The document cited in paragraph 79 speaks for itself and should be read as a whole.
 - 80. Admitted.
 - 81. Denied.
- 82. Admit only that Abbott is the licensee from Fournier of the '726 Patent ("Curtet Patent") and the '670 Patent, the '405 Patent, the '552 Patent, and the "881 Patent (collectively, the "Stamm Patents"). Abbott otherwise denies the allegations in paragraph 82.
- 83. Admit only that paragraph 83 purports to describe Teva's Amended Counterclaim and an unidentified Reginault document. Abbott states that those documents speak for themselves. Abbott otherwise denies the allegations in paragraph 83.
 - 84. Denied.
- 85. The allegation in paragraph 85 regarding "30 month stays" is a legal conclusion that requires no answer. Abbott otherwise denies the allegations in paragraph 85.
 - 86. Denied.
- 87. Paragraph 87 contains narrative description and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 87.
- 88. Paragraph 88 contains narrative description and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 88.
- 89. Admit only that Teva is producing and marketing a branded capsule product under the tradename Lofibra. Abbott is without sufficient knowledge or information to form a belief as to the truth of the allegations concerning Teva's sales, customer returns and its business, therefore denied. Abbott otherwise denies the allegations in paragraph 89.

- 90. Paragraph 90 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 90.
 - 91. Denied.
- 92. Paragraph 92 contains narrative description and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 92.
- 93. Admit only that (i) the new TriCor tablet formulation, unlike the original tablet formulation, does not need to be taken with food, (ii) approximately one-third of patients were not compliant in taking the original tablet formulation with food as directed, and (iii) the new TriCor tablet formulation and the original tablet formulation were bioequivalent under fed conditions. Abbott otherwise denies the allegations in paragraph 93.
- 94. Admit only that paragraph 94 purports to describe and contain search results from an online drug retailer's website. Abbott states that the website speaks for itself. Abbott otherwise denies the allegations in paragraph 94.
- 95. Admit only that paragraph 95 purports to describe and contain search results from an online drug retailer's website. Abbott states that the website speaks for itself. Abbott otherwise denies the allegations in paragraph 95.
- 96. Admit only that paragraph 96 purports to describe and contain search results from an online drug retailer's website. Abbott states that the website speaks for itself. Abbott otherwise denies the allegations in paragraph 96.
 - 97. Denied.
- 98. Paragraph 98 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 98.

- 99. Admit only that plaintiffs purport to bring this action on behalf of themselves and others similarly situated and purport to define a class. Abbott denies that class treatment is proper in this case. Abbott denies the remaining allegations in paragraph 99.
 - 100. Denied.
 - 101. Denied.
 - 102. Denied.
- 103. Abbott is without sufficient knowledge or information to form a belief as to the truth of the allegations regarding whether plaintiffs' counsel are experienced in antitrust and consumer class action litigation. Abbott otherwise denies the allegations in paragraph 99.
 - 104. Denied.
 - 105. Denied.
 - 106. Denied.

COUNT I

INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

- 107. Abbott repeats and realleges its responses to paragraphs 1-106 as though set forth herein.
 - 108. Denied.
 - 109. Denied.
- 110. Admit only that plaintiffs purport to seek equitable and injunctive relief.

 Abbott otherwise denies the allegations in paragraph 110.

COUNT II

FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

- Abbott repeats and realleges its responses to paragraphs 1-110 as though 111. set forth herein.
 - 112. Denied.
 - 113. Denied.
- 114. Admit only that plaintiffs purport to seek damages. Abbott otherwise denies the allegations in paragraph 114.

COUNT III

FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS

- 115. Abbott repeats and realleges its responses to paragraphs 1-114 as though set forth herein.
 - Denied. 116.
 - 117. Denied.

COUNT IV

UNFAIR AND DECEPTIVE TRADE PRACTICES IN VIOLATION OF THE DELAWARE CONSUMER FRAUD ACT

- Abbott repeats and realleges its responses to paragraphs 1-117 as though 118. fully set forth herein.
 - 119. Denied.
 - Denied. 120.
 - 121. Denied.
 - Denied. 122.

COUNT V

UNFAIR AND DECEPTIVE TRADE PRACTICES IN **VIOLATION OF ALL STATES' CONSUMER PROTECTION ACTS**

- 123. Abbott repeats and realleges its responses to paragraphs 1-122 as though set forth herein.
 - Denied. 124.
 - 125. Denied.

ADDITIONAL DEFENSES

FIRST ADDITIONAL DEFENSE

Plaintiffs fail to state a claim against Abbott upon which relief may be granted.

SECOND ADDITIONAL DEFENSE

Plaintiffs have not suffered, and will not suffer, injury of the type that the antitrust laws are designed to prevent, or any other injury to a legally cognizable interest, by reason of the conduct alleged in the End Payors' Complaint.

THIRD ADDITIONAL DEFENSE

At all times, Abbott has acted in good faith in furtherance of its legitimate business interests and has caused no injury to competition, the public, or plaintiffs.

FOURTH ADDITIONAL DEFENSE

Abbott's conduct is protected under the Noerr-Pennington doctrine and/or otherwise under the Constitution of the United States.

FIFTH ADDITIONAL DEFENSE

Plaintiffs' claims are precluded, in whole or in part, by the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984 and related amendments.

SIXTH ADDITIONAL DEFENSE

To the extent there is a finding of conduct that prevented generic entry and higher prices as a result, plaintiffs' claims are barred, in whole or in part, to the extent any higher prices were passed on, in whole or in part, to parties not included in the putative class.

SEVENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs would be unjustly enriched if allowed to recover all or any part of the damages alleged in the End Payors' Complaint.

EIGHTH ADDITIONAL DEFENSE

Plaintiffs' claims fail to comply with the pleading requirements of Rules 8 and 9(b) of the Federal Rules of Civil Procedure.

NINTH ADDITIONAL DEFENSE

Plaintiffs did not suffer injury or damages by reason of any act or omission by Fournier.

TENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs failed to mitigate their damages.

ELEVENTH ADDITIONAL DEFENSE

Any injuries, losses, or damages suffered by plaintiffs were proximately caused by their own actions regardless of whether contributory, negligent, incompetent, careless or reckless.

TWELFTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs alleged damages, if any, are speculative.

THIRTEENTH ADDITIONAL DEFENSE

Abbott does not maintain monopoly power in the relevant market.

FOURTEENTH ADDITIONAL DEFENSE

The Food and Drug Administration approved each version of TriCor for sale in the United States.

FIFTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because this action is not properly maintainable as a class action.

SIXTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because there have been no classwide damages as alleged by plaintiffs.

SEVENTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because they contravene the rule of law established by the United States Supreme Court in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977).

EIGHTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statute of limitations and/or laches.

NINETEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because of waiver and/or estoppel.

TWENTIETH ADDITIONAL DEFENSE

Abbott reserves the right to add to its additional defenses as additional information becomes available in the course of this litigation.

RELIEF REQUESTED

WHEREFORE, Abbott, having answered, respectfully requests judgment dismissing with prejudice the End Payors' Complaint and each and every claim for relief therein, and awarding Abbott its costs, disbursements, attorneys' fees and such other and further relief as the Court deems just and proper.

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Dated: July 21, 2006

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on July 21, 2006, the foregoing were caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on July 21, 2006 upon the following parties:

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The undersigned also hereby certifies that on July 21, 2006, true and correct copies

of the foregoing were caused to be served by hand upon the following local counsel:

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